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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,075	07/13/2001	Avi Ashkenazi	10466/42	9210

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1649

DATE MAILED: 07/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/905,075

Applicant(s)

ASHKENAZI ET AL.

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44-46, 49 and 52-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 44-46, 49, 57 and 58 is/are allowed.
- 6) ☒ Claim(s) 52-56, 59 and 60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/7/5</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Formal matters

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649.

Response to Amendment

2. Claims 52-56 have been amended as requested in the amendment filed on May 27, 2005. Claims 44-46, 49 and 52-60 are pending in the instant application.

Claims 44-46, 49 and 52-60 are under examination in the instant office action.

3. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. Applicant's arguments filed on May 27, 2005 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112

6. Claims 52-56 and 59-60, as amended, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the full length of the polypeptide of SEQ ID NO: 2, which inhibits VEGF stimulated proliferation of adrenal cortical capillary endothelial cells, does not reasonably provide enablement for any other molecular embodiment that lacks the

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amino acid sequence of SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 52-56 and 59-60, as amended, are directed to isolated polypeptides that are at least 80%, 95%, 99% identical to the polypeptide of SEQ ID NO: 2, wherein said polypeptides inhibit VEGF stimulated proliferation of endothelial cells. The instant specification discloses that the instant polypeptide of SEQ ID NO: 2, PRO211 is capable of inhibition of VEGF stimulated proliferation of adrenal cortical capillary endothelial cells. However, the instant specification, as filed, fails to provide enough guidance on how to make polypeptides with limited structural similarity to the polypeptide of SEQ ID NO: 2, said polypeptides capable of inhibiting VEGF stimulated proliferation of endothelial cells.

Applicant traverses the rejection on the premises that the instant specification provides guidelines and protocols for the VEGF proliferation assay as well as methods of determination of percent identity between two amino acid sequences (page 9 of the Response). Applicant's arguments have been fully considered but are not persuasive for the following reasons.

Applicant has taken the position that 35 U.S.C. 112, first paragraph, permits an artisan to present claims of essentially limitless breadth as long as the specification provides one with the ability to test any particular embodiment, which is encompassed by the material limitations of a claim and thereby distinguish between those embodiments which meet the functional limitations from those embodiments which don't. This argument is not entirely without merit. However, the issue here is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the

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instant specification and the prior art of record. Applicant's "make and test" position is inconsistent with the decisions *In re Wands*, 8 USPQ2d, 1400 (CAFC 1988), which was cited as the judicial basis for the instant rejection in the previous office action, and in *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), which held that

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved" (emphasis added). In the instant case, the specification suggests that the polypeptide of SEQ ID NO: 2 is related to EGF family of cytokines, which is known for great diversity of biological functions (see reasons of record in section 7 of Paper mailed on October 02, 2002, for example). Therefore, while one can easily produce a polypeptide, which is 80%-99% identical to the instant polypeptide of SEQ ID NO: 2, one would have no idea how to produce a polypeptide, which also inhibits VEGF stimulated proliferation of endothelial cells.

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The instant specification is not enabling because one can not following the guidance presented therein and make the claimed polypeptides without first making a substantial inventive contribution.

7. Claims 52-56 and 59-60, as amended are further rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 52-56 and 59-60, as amended, are directed to isolated polypeptides that are at least 80%, 95%, 99% identical to the polypeptide of SEQ ID NO: 2, wherein said polypeptides inhibit VEGF stimulated proliferation of endothelial cells. As fully explained in the previous office actions of record, the claims do not require that the polypeptides possess any particular conserved structure or other disclosed distinguishing feature and the instant specification fails to describe the entire genus of proteins, which are encompassed by these claims. Applicant submits that "the specification in Example 66 provides guidance for identifying polypeptides with this functional activity" (middle at page 10 of the Response). However, the issue at hand remains that the instant specification is only limited to description of one protein having the amino acid sequence of SEQ ID NO: 2 and provides no written description of any other protein which lacks the amino acid sequence of SEQ ID NO: 2 and has any relevance to PRO211 protein. In the absence of sufficient recitation of distinguishing identifying characteristics of the claimed genus of polypeptides, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore one would reasonably conclude that at the

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time of invention Applicant was not in possession of the claimed invention (*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111).

Conclusion

8. Claims 44-46, 49 and 57-58 are allowed. Claims 52-56 and 59-60 are rejected.
9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

July 16, 2005